



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/405,839	09/27/1999	SIMON WILLIAM JONATHAN BRIGHT	PM-263754	9963

909 7590 10/02/2003

PILLSBURY WINTHROP, LLP
P.O. BOX 10500
MCLEAN, VA 22102

EXAMINER

HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
----------	--------------

1638

29

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/405,839

Applicant(s)

BRIGHT ET AL.

Examiner

Georgia L. Helmer

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39, 43 and 76-91 is/are pending in the application.
- 4a) Of the above claim(s) 76-91 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Restriction election

1. The Office acknowledges the receipt of Applicant's Response and Restriction Election, Paper No. 29, filed 24 June 2003.
2. Applicant elects Group I claims 39, 40, 28, 41-45 and 52, with traverse, stating that the methods claims of newly added claims 76-91 encompass the nucleic acid expression system of claims 39 and 41 and therefore should be examined with these latter claims. Applicant's traversal has been considered and is unpersuasive because the claims of Group I are properly restricted, as discussed below, and new claims 76-91 represent a new invention. Applicant traverses, stating primarily that claim 27 of Groups II is related to group I and should be examined with that group. Applicant's traversal has been considered and is persuasive. Group I claims and claim 27 should be examined together as one group. However, claim 27 has been cancelled. Applicant asserts that new claim 86 is substantially the same as claim 27 and should be examined with Group I claims. Applicant's traversal has been considered and is unpersuasive because claim 27 is drawn to an expression system and new claim 86 is drawn to a method. These claims are appropriately restricted. Applicant traverses, stating primarily that Group III and Group I claims are not independent because there is not evidence given by Examiner for this. New claims 87-91 correspond to group II claims but depend on new claims 76-79. Applicant asserts that there is not evidence presented that group III genomes can be made by any process other than new claim 76-79. Applicant's traversal has been considered and is unpersuasive because claims of group III are drawn isolated genomes, not to isolated complete genomes, and read on a partial

genome. The partial genome does not necessarily carry heterologous DNA and therefore can be derived from a wild-type plant. This restriction is made Final.

3. Claims 1-38, 40-42, 44-75 are cancelled. Therefore, of the original claims, 39 and 43 are pending. Applicant has added claims 76-91, drawn to a method of controlling whether a characteristic is displayed in a plant, plants and plant seed. Newly submitted claims 76-91 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Inventions of claims 39 and 43 and the inventions of claims 76-91 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product—the expression system nucleic acids can be used as hybridization probes.

4. Original Claims 39 and 43 and newly added claims 76-91 are pending. Claims 76-91 are withdrawn as being drawn to a nonelected invention.

Claim Rejections - 35 USC § 112, second paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 39 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claims 39 and 43 are ambiguous because these claims are unduly alternative: to an expression system comprising components (a)+ [(b)i or (b)ii] and (c) and (d). The metes and bounds of this claim are not apparent, and the meaning of the claim is ambiguous.
- In these claims, "gene" is unclear because a "gene" implies a DNA sequence that exists in nature and includes coding and noncoding regions, as well as all regulatory sequences associated with expression. Since this does not appear to be Applicant's intention, the language "a DNA of interest" is suggested. Or Applicant may recite the various components of the "gene" desired. All recitations of "gene" are also rejected.

- In claim 39, line 16, "adapted" is unclear. What adaptation is envisioned? Claim 43 is drawn to an expression system comprising "the promoter of the AlcA gene, the system further comprising a gene capable of expressing the AlcR protein, alcA and alcR being obtainable from *Aspergillus*." What does this mean? Furthermore, "obtainable" should be replaced by "obtained", since no conditions are set forth for "obtainable".

Clarification and/or correction are required.

Claim Rejections - 35 USC § 112, first paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written description

8. Claim 43 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 43 is drawn to an expression system comprising "the promoter of the AlcA gene, the system further comprising a gene capable of expressing the AlcR protein, alc A and alcR being obtainable from *Aspergillus*". No structural or functional description is given of "AlcA gene, the system further comprising a gene capable of expressing the AlcR protein". Applicants are claiming a genus of sequences, yet there is no description of the structural features that define the genus.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), where it states: "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA Accordingly, the specification does not provide a written description of the invention"

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed. (see Written Description Requirement published in Federal Register/Vol.66, No. 4/ Friday, January 5, 2001/Notices; p. 1099-1111.)

Enablement – Deposit requirement

Claim 43 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 43 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 43 is drawn to an expression system comprising "the promoter of the AlcA gene, the system further comprising a gene capable of expressing the AlcR protein, alc A and alcR being obtainable from *Aspergillus*". The specification lacks sufficient evidence that the claimed biological material – the "promoter of the AlcA gene, the system further comprising a gene capable of expressing the AlcR protein, alc A and alcR-- is either 1) reproducible, 2) known and readily available to the public, or 3) deposited in compliance with 37 CFR 1.801-1.809. If the claimed biological material was deposited under the provisions of the Budapest treaty, Applicant must provide a declaration stating that the claimed biological material was made under the provisions of the Budapest treaty in compliance

Art Unit: 1638

with 37 CFR 1.801-1.809, and that all restrictions imposed by the depositor on the availability to the public of the deposited biological material will be irrevocably removed upon the grant of the patent. Applicant's attention is directed to 37 CFR §§1.801-1.809, MPEP §§ 2402-2411.05 and In re Lundak 773 F.2d 1216, 227 USPQ 90 (Fed. Cir. 1985) for further information concerning the Rules and Regulation for Deposit of Biological Materials for Patent Purposes.

Enablement

9. Claims 39 and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)): the enablement issue is the use of recombinase systems to excise DNA sequence.

Nature of the invention. Applicant's claims are drawn to a method of producing a transgenic plant which temporarily convey a phenotypic trait to a plant, comprising constructing a gene cassette comprising a DNA sequence conferring a trait, one or more DNA sequences expressing a recombinase-type protein, at least one pair of DNA excision sequences flanking the heterologous DNA and a transiently active promoter operably linked to the DNA sequence expressing the recombinase-type protein such that when the promoter is activated, the recombinase is expressed; introducing the cassette into a plant and expressing the DNA sequences with the cassette to a stimulus

Art Unit: 1638

that activates the promoter and the recombinase excises the heterologous DNA from the plant genome. The claimed methods use recombinase-type systems to modify gene expression.

State of the prior art and the predictably of the art. Recombinase mediated excision of appropriately flanked DNA sequences is variable and yields chimeric phenotypes having both recombined and unrecombined DNA (Gidoni, D. et al, Supplement to Plant Molecular Biology Reporter 18:2, S 03-40; ISPMB abstracts, June 18-24, 2000). Recent studies (Gidoni, D et al (2001) Euphytica 121: 145-156) of embryonal recombination and germline inheritance of recombined tobacco loci show variable recombination efficiencies (Godini 2001, 146 and 152). The claimed methods require use of recombinase-type systems to delete appropriately flanked DNA sequences.

Breadth of the claims. Claims are broadly drawn to any recombinase, any plant, any trait and any marker gene. Recombinases and recombinase sites are encompassed broadly; Applicant describes site specific recombinases, but claims all recombinases.

Working examples. There are no working example exemplification of the use of recombinase systems to excise DNA sequences.

Guidance in the specification. Working examples. The specification contains four examples, three working examples and one prophetic example. There are no working examples of the use of recombinase systems to excise DNA sequences.

Example 1 describes (p 19) construction of a malate synthase promoter including lac I operator sequences. Example 2 (p. 20) describes the construction of a plant transformation vector pPOP1 and transformation of tobacco. Example 3 (p. 25) demonstrated that the modified malate synthase promoter including lac I operator sequences targets gene expression to germinating seedlings. Prophetic Example 4 (p. 26) describes how to demonstrate FLP mediated excision of a FRT flanked PAT gene and suppression of this effect using an inducible repressor gene. Only Example 4 is relevant to the current claims, as it is the only examples which includes a recombinase system. Furthermore, Applicant gives not information on how to use the AlcA and alcR genetic sequences to produce the claimed desired constructs.

Applicant describes a series of steps that one of skill in the art could take to try to produce an expression system having specific desired properties. These properties are all predicated on the ability of a recombinase gene being expressed and successfully excising a DNA specific sequence from a DNA sequence flanked by DNA recombinase excision sequences. If the DNA excision reactions do not function faithfully and at a very high frequency, none of the more complicated steps of the multi-tiered cascade, will function as desired. Applicant describes a recombinase containing construct, but gives no results.

Amount of Experimentation necessary. Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden.

In view of the breadth of the claims (to any recombinase, any plant, any trait and any marker gene), the lack of guidance in the specification, and the unpredictability in the recombinase art, undue trial and error experimentations would be required to enable the invention as commensurate in scope with the claims.

Remarks

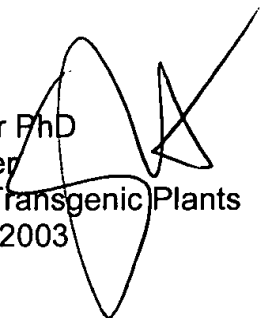
10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia Helmer PhD
Patent Examiner
Art Unit 1638, Transgenic Plants
September 28, 2003




ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600